IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

ENDO PHARMACEUTICALS INC., Plaintiffs, v. ROXANE LABORATORIES, INC., Defendant.	C.A. No. 13-cv-3288-TPG

REPLY MEMORANDUM IN SUPPORT OF ROXANE LABORATORIES, INC.'S MOTION *IN LIMINE* REQUESTING THAT THIS COURT, ON COLLATERAL ESTOPPEL GROUNDS, PRECLUDE ENDO PHARMACEUTICALS INC. FROM TAKING POSITIONS INCONSISTENT WITH THE FEDERAL CIRCUIT IN *In re Kao*, 639 F.3d 1057 (Fed. Cir. 2011)

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Introduction

The Court should not allow Endo to relitigate the many subsidiary factual issues identified in Roxane's motion relevant to the issues of obviousness of the '122 and '216 patent claims. The Federal Circuit has already determined what the Maloney reference teaches about extended-release oxymorphone compositions, the inherency of the pharmacokinetic and food-effect properties of oxymorphone, and the enablement of Maloney. Endo identifies no compelling reason why it deserves another shot at relitigating these same factual issues in yet another forum.

Endo's brief battles with straw men. Contrary to Endo's intimation, Roxane is not seeking to accord collateral-estoppel effect to some imagined holding in the Federal Circuit that the '122 and '216 patent claims are obvious, for there was no such holding. Instead, Roxane is merely seeking to save this Court from having to waste its time hearing Endo's attempt to have a second bite at the apple on certain factual findings about what the relevant prior art describes and the inherency of pharmacokinetic properties that the Federal Circuit already determined after full and fair litigation.

I. The different burdens of proof do not come into play here because Roxane only seeks to prevent the Court from having to determine certain underlying facts that the Federal Circuit already found.

Endo obviously can offer no good reason for making the Court spend its valuable time relitigating straightforward factual matters like what the prior art Maloney reference teaches when the Federal Circuit has already made that determination. So instead, Endo tries to distract the Court by focusing on the different burdens of proof applied in *Kao* and in this Court.

But Roxane is not seeking to preclude Endo from arguing the validity of the '122 and '216 patent claims. If it were, the distinction Endo draws about the different burdens of proof in the two actions might be relevant.

Instead, at minimum, Roxane seeks to prevent the Court and parties from consuming valuable trial time replowing old ground concerning what the Maloney reference teaches, where the Federal Circuit has already found what that reference discloses, as spelled out in detail at pages 5-6 of Roxane's motion *in limine*. Those findings include:

- "Maloney teaches a controlled release opioid formulation comprising an opioid compound in amounts of 5–100 mg." *Id.* at 1071;
- "Maloney further discloses that oxymorphone is a preferred opioid compound." *Id*.;
- "Maloney discloses that its dosage form provides a dissolution rate of 60%–80% active agent released after 12 hours. Based on these findings, the Board reasonably concluded that Maloney's active agent would still be effective after 12 hours because it is still being released from Maloney's dosage form at 12 hours. . . . Substantial evidence supports the Board's conclusion that the oxymorphone formulation disclosed in Maloney would satisfy the claimed 12–hour effectiveness limitation." *Id.*;
- "Substantial evidence supports the Board's finding that Maloney teaches a controlled release formulation using both hydrophobic and hydrophilic materials." *Id.*;
- "It is undisputed that Maloney discloses a method of providing extended pain relief by the provision of a therapeutically effective amount of controlled release oxymorphone." *Id.* at 1072;
- "This court agrees with the Office. Substantial evidence supports the Board's finding, based upon the specification, which confirms that the claimed "food effect" is an inherent property of oxymorphone itself, present both in controlled release and immediate release formulations of that drug." *Id*. at 1070;
- "The only evidence of record indicates that the unexpected *in vivo* characteristics [multiple peaks] of oxymorphone controlled release compositions did not result from properties unique to any specific commercial embodiment." *Id*. at 1068-69.

II. Endo has not shown that any differences between the claim terms at issue in *Kao* and those here affect the obviousness analysis.

Endo's argument regarding non-identity of exact claim language is a red herring. As this Court has explained, "[i]n a patent infringement action, it is not necessary that the claims

asserted be identical to the previously adjudicated claims in order for collateral estoppel to apply." *Endo Pharms. Inc. et al. v. Teva Pharms. USA, Inc. et al.*, No. 12-cv-8060 (TPG), D.I. 148 at 4 (S.D.N.Y. Mar. 17, 2015) (*citing Ohio Willow Wood Co. v. Alps S., LLC*, 735 F.3d 1333, 1342 (Fed. Cir. 2013)).

Rather, as Endo's own cited case law establishes, in order for any differences in claim terms to affect the collateral-estoppel analysis, those differences must be "material to how prior art applies." (Opp. Br. at 11, citing *PPC Broadband, Inc. v. Corning Gilbert Inc.*, 995 F. Supp. 2d 104, 108-09 (S.D.N.Y. 2014)). Endo has not shown material differences in that respect. Endo cannot and does not deny that the patents-in-suit here and the applications in *Kao* are related. And while every claim is not identical word-for-word, the chart in Roxane's motion *in limine* shows that many or most of the claim *limitations* at issue are common to both cases. For example, Endo's Footnote 1 quotes the C_{max} limitation that was at issue in *Kao*, which is, save for a word or two, the same limitation found in Roxane's chart showing '216 patent claim 40. Since the applications in *Kao* and the claims here are from the same family and share common limitations, the findings in *Kao* regarding what the Maloney reference teaches are relevant to this case irrespective of whether the claims in both cases are verbatim "identical."

In arguing that the claims in the patents-in-suit are not word-for-word identical to the applications in *Kao*, Endo overlooks that Roxane's motion is limited to the Federal Circuit's findings about what the prior art, specifically Maloney, teaches. Thus, it is irrelevant whether the claims in suit are not word-for-word identical to the claims in the applications at issue in *Kao*.

III. Endo's "new facts" are not material.

Endo's opposition brief cites supposed "new facts" that purportedly preclude application of collateral estoppel, namely deposition testimony of a Roxane non-infringement—but not

invalidity—expert as to whether C_{max} and AUC food effect limitations are inherent properties of oxymorphone and certain deposition testimony of Amneal's expert.

The Court should not be persuaded by this testimony, which Endo offers as a distraction from the issues. Neither of these individuals are invalidity/obviousness experts.

Moreover, while prosecuting the patent applications, Endo already tried to say that the food effects were not inherent, but the Federal Circuit found otherwise—and it is well-established law that "an obvious formulation cannot become nonobvious simply by administering it to a patient and claiming the resulting serum concentrations . . . To hold otherwise would allow any formulation—no matter how obvious—to become patentable merely by testing and claiming an inherent property." *Santarus, Inc. v. Par Pharm, Inc.*, 694 F.3d 1344, 1354 (Fed. Cir. 2012).

For these reasons, these witnesses' testimony is not material to any obviousness issue and cannot preclude application of collateral estoppel.

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Respectfully Submitted,

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CERTIFICATE OF SERVICE

I, Paul B. Sudentas, hereby certify that on March 19, 2015, a true and correct copy of the foregoing REPLY MEMORANDUM IN SUPPORT OF ROXANE LABORATORIES, INC.'S MOTION *IN LIMINE* REQUESTING THAT THIS COURT, ON COLLATERAL ESTOPPEL GROUNDS, PRECLUDE ENDO PHARMACEUTICALS INC. FROM TAKING POSITIONS INCONSISTENT WITH THE FEDERAL CIRCUIT IN *In re Kao*, 639 F.3d 1057 (Fed. Cir. 2011) was electronically served by email upon the following counsel:

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